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APPLICATION NO.	EXAMINER	DEPT. NAME & ADDRESS	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15,157,191	15/002201	Wanda L. Wondy	15/002201	1701
EXAMINER 15/002201		ART UNIT 15/002201		
DATE MAILED 05/05/05				

Richard R. Eckman  
 Morris & Funder LLP  
 755 Page Mill Road  
 Palo Alto, CA 94304-1016

Please find below and/or attached an Office communication concerning this application or proceeding.

Docketed: ES  
 Reminder: 10/13/04 1st Ext  
 Final Due Date: 12/13/04

PTO DOC (Rev. 10-05)

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MAY 05 2005

## Office Action Summary

Application No.

10057.187

Applicant(s)

WENSLEY ET AL

Examiner

Darwin P. Eisele

Art Unit

3761

The MAILING DATE of this communication appears on the cover sheet with the correspondence address -  
 Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be made under the provisions of 37 CFR 1.136(a), as amended, however, no extension of time may be made under 37 CFR 1.136(b) for the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory maximum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTH(S) from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 113)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may require any needed patent term adjustment. See 37 CFR 1.104(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004  
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213

## Disposition of Claims

- 4) ☒ Claim(s) 1-85 and 124-134 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☒ Claim(s) 39-43, 46-53, 56, 57, 65 and 124-130 is/are allowed.  
 6) ☒ Claim(s) 1-70, 74, 76-78, 30, 31, 44-47, 54, 55, 58-64 and 131-133 is/are rejected.  
 7) ☒ Claim(s) 10-13, 15, 29, 31-35, 37 and 38 is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(e)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of Reference Cited (PTO-892)  
 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-944)  
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/ISD/US)  
 Paper No./Mkt Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
 Paper No./Mkt Date \_\_\_\_\_  
 5) ☐ Notice of Informal Patent Application (PTO-152)  
 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 28 recites the limitation "the surface" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:  

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 1-5, 7-9, 14, 16, 18-28, 30, 36, 44-46, 54, 55, 59, 61-64 and 131-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,146,915 to Montgomery in view of US 5,894,841 to Voges.
6. As to claims 1, 18, 20, 30 and 54 Montgomery teaches a method for generating an aerosol comprising the steps of heating a physiologically active compound to vaporize at least a portion of said compound and mixing the resulting vapor with a

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carrier gas (col. 2, lines 33-58) in a desired concentration (col. 2, lines 62-65); wherein the carrier gas is air (col. 1, line 9); wherein the compound is heated to a temperature for a period of time; wherein the compound is heated in a container (chamber) and passes to an orifice 4; and administering the aerosol to the patient.

Montgomery is silent with regards to the method comprising the step of mixing the vapor with the carrier gas in a ratio to form a desired particle size when a stable concentration of particles in the gas is reached.

Vogas teaches that the droplet size of an aerosol delivered to a patient is a function of the carrier gas pressure and velocity (col. 1, lines 43-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Montgomery to include the step of mixing the resulting vapor with a carrier gas in a ratio to form a desired particle size since Vogas teaches that it is well known in the art to control the particle size since the particle size is a function of the delivered pressure and velocity of the carrier gas, i.e., controlling the pressure and velocity of the carrier gas will alter the ratio of vapor to carrier gas. Furthermore, constant application of the same pressure and velocity of the carrier gas would produce aerosol with the same particle size, thus producing a stable concentration (inherent via the function of the pressure and velocity of the carrier gas in relation to the vapor).

7. As to Claims 2 and 5, the above combination teaches controlling the ratio of the vapor to gas by regulating the flow of said gas (pressure and velocity of the carrier gas).

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8. As to claims 3, 4, 7-9, the above combination is silent with regards to specifically controlling the ratio of vapor to gas via the rate of vaporization by controlling the energy transferred to the compound during the heating step. However, this would have been an obvious step to one of ordinary skill in the art at the time the invention was made since Montgomery teaches an adjustable heater (col. 3, lines 26-27), which would inherently regulate the rate of vaporization.

9. As to claim 14, the above combination teaches depositing the compound into a substrate (the vaporizing chamber 12 of Montgomery) prior to heating.

10. As to claims 16 and 46, the above combination teaches the particle size in the range of about 1-3 microns (col. 5, lines 3-4 of Voges).

11. As to claim 19, the above combination teaches a nicotine compound (col. 3, line 2 of Voges).

12. As to claims 21-22, the above combination discloses the claimed invention except for recited range of time. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the recited range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

13. As to claims 23 and 26, the above combination teaches the gas mixed at a closely controlled flow rate in order to maintain a stable concentration of particle size.

14. As to claim 24, Montgomery teaches preventing the increasing in gas temperature by mixing the carrier gas (col. 3, line 54 - col. 4, line 2).

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15. As to claim 25, the above combination is silent with regards to the gas temperature increase no greater than 15°C but is inherent since Montgomery teaches a method that prevents the increase in gas temperature.

16. As to claim 27, the above combination teaches a laminar flow that is maintained across the surface of the compound in order to maintain a stable concentration of particle size.

17. As to claim 28, Fig. 2 of Montgomery shows a gas flow that is turbulent (venturi effect).

18. As to claim 36, the above combination discloses the claimed invention except for recited range of the surface area. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the recited range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Alter*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

19. As to claim 44, Montgomery teaches the compound deposited into a thermally conductive substrate since chamber 12 includes heaters 32.

20. As to claim 45, the above combination teaches the compound contained in heating-vaporization zone (vaporizing chamber 12) and rapidly mixing the vapor with the carrier gas at a desired ratio as mentioned in the rejection of claim 1.

21. As to claim 55, the above combination teaches continuously introducing a compound into the vaporizing chamber since it is inherent that the vaporizing chamber is fully capable of being refilled.

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22. As to claim 59, Montgomery teaches a substrate (the vaporizing chamber 32) having a plurality of sections that are heated (heaters 32).

23. As to claims 61-64, Montgomery is silent with regards to the operation of the heaters. However, it would have been obvious to one of ordinary skill in the art to use any well known heaters, including inductive, thermal, dielectric or resistive heaters, since these heaters are well known in the art.

24. As to claims 131-134, it is well known in the art to use vaporizers to provide mist to a user's eye, skin or mucousa and would have been obvious to one of ordinary skill in the art.

25. Claims 6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of Voges, and in further view of US 4,484,576 to Albarda.

The above combination of Montgomery/Voges is silent with regards to an annunciating signal when the flow rate of the carrier gas is out of range. Albarda teaches a medical device having a flow of respiratory gas, wherein the flow of respiratory gas includes a warning lamp or annunciating signal (col. 4, line 25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of the above combination to include the use of a warning lamp since it is beneficial to alert the user the user/patient if the device is malfunctioning or operating outside the normal parameters.

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26. Claims 17 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of Voges, and in further view of US 5,874,841 to Weers et al.

The above combination of Montgomery/Voges is silent with regards to the particle size in the range of 10 nm to 100 nm. Weers teaches that is known in the respiratory art to have particle sizes in the range of 10 nm to 100 nm (col. 5, line 6). Therefore, it would have been obvious to one of ordinary art at the time the invention was made to modify the steps taught by the above combination to include the particle size range of 10 to 100 nm since Weers teaches that the recited range is known in the art and would be dependent upon the intended therapy.

27. Claims 58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of Voges, and in further view of US 6,090,212 to Mahawili.

The above combination teaches all the limitations of the claim, as recited in the above rejections, but is silent with regards to a heater means comprising changing the focus of photon energy. Mahawili teaches a heater wherein the photon energy is used to provide heat. Therefore, it would have been obvious at the time the invention was made to use the heater of Mahawili in the method of Montgomery/Voges, since it is well within the scope of one ordinary skill in the art to replace Montgomery's heater with any well known heater, including the heater of Mahawili.



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*Allowable Subject Matter*

28. Claims 10-13, 15, 29, 31-35, 37 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
29. Claims 39-43, 48-53, 56, 57, 65 and 124-130 are allowed.

*Response to Arguments*

30. Applicant's arguments with respect to claims 1-10, 14, 16-28, 30, 36, 44-47, 54, 56, 58-64 and 131-134 have been considered but are moot in view of the new ground(s) of rejection.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on (703)308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

de

*Glenn*  
GLENN K. DAWSON  
PRIMARY EXAMINER

**COPY**

PTO/SB/21 (08-03)  
Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<h2 style="margin: 0;">TRANSMITTAL FORM</h2> <p style="margin: 5px 0;">(to be used for all correspondence after initial filing)</p>		Application Number	10/057,197	
		Filing Date	October 26, 2001	
		First Named Inventor	Martin J. WENSLEY	
		Art Unit	3761	
		Examiner Name	D. Erezzo	
Total Number of Pages in This Submission		4	Attorney Docket Number	509032001500

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 1. Request for Withdrawal as Attorney or Agent and Change of Correspondence Address (in triplicate) - 3 pages 2. Return Receipt Postcard
<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;">Remarks</div> <div style="width: 70%; text-align: center;"> <h3 style="margin: 0;">FAX RECEIVED</h3> <p style="margin: 5px 0;">MAY 05 2005</p> <p style="margin: 0;">OFFICE OF PETITIONS</p> </div> </div>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	MORRISON & FOERSTER LLP (Customer No. 25226) Thomas E. Ciotti - 21,013
Signature	<i>Thomas E. Ciotti</i>
Date	May 20, 2004

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.	
Dated: 5/21/04	Signature: <i>Thao T. Pham</i> (Thao T. Pham)

NO DOCKETING REQUIRED

MAY-05-05 03:24PM FROM-

T-113 P.019 F-188



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,197	10/26/2001	Martin J. Wensley	509032001500	1701
7590 01/12/2005				
Mika Mayer Morrison & Foerster LLP 755 Page Mill Road Palo Alto, CA 94304-1018				
			EXAMINER EREZO, DARWIN P	
			ART UNIT 3731	PAPER NUMBER

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

FAX RECEIVED  
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OFFICE OF PETITIONS

Docketed: 1/11 2-8-2005

Application No.

10/057,197

Applicant(s)

WENSLEY ET AL.

Examiner

Darwin P. Erez

Art Unit

3731

## Office Action Summary

The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-13, 15, 29, 31-35, 37-43, 48-53, 56, 57, 65 and 124-130 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10, 11, 39-43, 48 and 124-130 is/are allowed.
- 6) ☒ Claim(s) 12, 15, 29, 31-35, 37, 38, 49-53, 56, 57 and 65 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

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OFFICE OF PETITIONS

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
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- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Page 2

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**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

**OFFICE OF PETITIONS**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2004/0016427 to Byron et al.

(claim 12) Byron teaches a method for generating an aerosol comprising the steps of moving a physiologically active compound into a heating-vaporization zone (paragraph 34) and heating the compound to vaporize at least a portion of the compound (paragraph 34); and mixing the resulting vapor with a gas, in a ratio (paragraph 56; the gas within the spacer chamber), wherein the ratio of vapor to gas is controlled by regulating the rate of vaporization (paragraph 51) and wherein the vaporization rate is controlled by changing the rate the compound is moved into the zone (intermittently) to form a desired particle size when a stable concentration of particles in the gas is reached.

(claim 15) Byron also teaches heating the physiologically active compound at a temperature below the boiling point (paragraph 34).

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***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 29, 50, 52, 56, 57 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,146,915 to Montgomery in view of US 5,894,841 to Voges.

(claim 29) Montgomery teaches a method for generating an aerosol comprising the steps of depositing a compound into a substrate (the vaporizing chamber 12 of Montgomery) prior to heating, sweeping gas across the film (via carrier gas, col. 2, lines 33-58); heating the compound to vaporize the compound (via heaters 32).

Montgomery is silent with regards to the method comprising the step of mixing the vapor with the carrier gas in a ratio to form a desired particle size when a stable concentration of particles in the gas is reached.

Voges teaches that the droplet size of an aerosol delivered to a patient is a function of the carrier gas pressure and velocity (col. 1, lines 43-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Montgomery to include the step of mixing the resulting vapor with a carrier gas in a ratio to form a desired particle size since Voges teaches that it is well known in the art to control the particle size since the particle size is a function of the delivered pressure and velocity of the carrier gas, i.e., controlling the pressure and velocity of the carrier gas will alter the ratio of vapor to

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Art Unit: 3731

carrier gas. Furthermore, constant application of the same pressure and velocity of the carrier gas would produce aerosol with the same particle size, thus producing a stable concentration (inherent via the function of the pressure and velocity of the carrier gas in relation to the vapor).

(claims 50, 52, 56, 57 and 65) Montgomery teaches a substrate that is heated sequentially (heater 32 has two prongs that are in sequence; a connected series); wherein the heaters are of the resistive/conductive type; and wherein the aerosol is administered to a patient.

5. Claims 31-35, 37, 38 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,146,915 to Montgomery in view of US 5,894,841 to Voges, and in further view of US 5,366,770 to Wang.

Montgomery teaches all the limitations of the claims, as recited in the rejection above, but fails to teach the compound being heated by moving the substrate through an alternating magnetic field (inductive). Wang teaches a vaporizer using magnetic fields to heat a compound (col. 4, lines 53-59) and the use of a mesh, metallic or stainless steel foil (col. 6, lines 51-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any well known heat step, including the heating step of Wang, since the applicant has not disclosed that the specific type of heating step solves any stated problems or is for any particular purpose and it appears that the invention would perform equally well with the step taught by Wang.



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Wang teaches the field maintained at 1 MHz but is silent with regards to 100-300 kHz. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the thickness in the recited range because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

6. Claims 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of Voges, and in further view of US 6,090,212 to Mahawili.

Montgomery teaches a substrate that is heated sequentially (heater 32 has two prongs that are in sequence; a connected series). However, the above combination of Montgomery/Voges is silent with regards to a heater means comprising changing the focus of photon energy. Mahawili teaches a heater wherein the photon energy is used to provide heat. Therefore, it would have been obvious at the time the invention was made to use the heater of Mahawili in the method of Montgomery/Vogue, since it is well within the scope of one ordinary skill in the art to replace Montgomery's heater with any well known heater, including the heater of Mahawili.

***Allowable Subject Matter***

7. Claims 10, 11, 39-43, 48 and 124-130 are allowed.

8. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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***Response to Arguments***

The indication of allowable subject matter in the previous office action is regretted and new grounds of rejections are set forth.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
GLENN K. DAWSON  
PRIMARY EXAMINER

**Notice of References Cited**

Application/Control No.

10/057,197

Applicant(s)/Patent Under  
Reexamination  
WENSLEY ET AL.

Examiner

Darwin P. Erez

Art Unit

3731

Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-2004/0016427	01-2004	Byron et al.	128/200.14
	B	US-6,263,872	07-2001	Schuster et al.	128/203.26
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,982	11/20/2003	Ron L. Hale	00057.01R	2735

7590

03/08/2005

IP Department  
Alexza MDC  
1001 East Meadow Circle  
Palo Alto, CA 94303

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/718,982

Applicant(s)

HALE ET AL

Examiner

Mina Haghighatian

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)

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### DETAILED ACTION

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20, 25, 28, 43-44, 48, 59-60, 62-63 and 74-79 rejected under 35

U.S.C. 102(e) as being anticipated by Byron et al (20040016427 A1).

Byron et al disclose a method and apparatus for generating an aerosol. The aerosol is formed by supplying a material in liquid form to a tube and heating the tube such that the material volatilizes and expands out of an open end of the tube. The volatilized material combines with ambient air such that volatilized material condenses to form the aerosol (see abstract and [0012]). The aerosols intended for inhalation typically have a mass median particle diameter of less than 2 microns (see [0074]). An example of a drug particle is budesonide ([0080]).

Byron et al disclose that the apparatus may be fairly large or may be miniaturized to be hand held (see [0086]).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Byron et al (20040016427 A1) in view of Bartus et al (6,514,482).

Byron, discussed above, lacks specific disclosure on medicaments.

Bartus teaches a method of pulmonary delivery of a medicament, which includes administering to the pulmonary system and in particular to the alveoli or the deep lung particles comprising an effective amount of a medicament, where the particles preferably have an aerodynamic diameter between about 1 and about 5  $\mu\text{m}$ . Particles can consist of the medicament or can further include one or more additional components. Rapid release of the medicament into blood stream and its delivery to its site of action (col. 3, lines 41-59).

Bartus discloses that medicaments which can be used in the said method include anti-inflammatory agents, anti-migraine agents, muscle relaxants, apomorphine, acetaminophen, lidocaine, diazepam, pindolol, diclofenac, valproic acid, flufenamic acid, isometheptene mucate, propoxyphene napsylate, luxapine succinate, etc (col. 5, line 35 to col. 7 line 20).

In a preferred embodiment, Bartus discloses that particles are delivered from an inhalation device, preferably they are administered via a dry powder inhaler (DPI),

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metered dose inhaler (MDI), nebulizers or instillation techniques. Various suitable devices and methods of inhalation which can be used are known in the art (col. 7, line 24 to col. 8, line 8).

Bartus discloses that at least 50% of the mass of the particles stored in the inhaler receptacle is delivered to a subject's respiratory system in a single breath activated step. Amounts of drug or medicament present in the particles can range from 1 to about 90 weight percent (col. 8, lines 26-41). Bartus lacks teachings on producing condensation aerosol and also lacks specific disclosure on the presence of less than 5% degradation products.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have implemented the medicaments of Barus et al in the aerosol device article of Byron et al for delivering the aerosolized compositions to a subject's respiratory tract because it would be desirable to provide a wide variety of therapeutic agents in an aerosol delivery article which is capable of producing condensate aerosol particles of relatively small size without the necessity of subjecting the material to be aerosolized to exposure to a significant degree of heat or high temperatures. Also noted that optimization of concentration ranges will not support patentability. Additionally, kits, including instructions are obvious and known to one of ordinary skill in the art.



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Claims 20-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faithfull et al (6,041,777) in view of Bartus et al (6,514,482).

Faithfull teaches methods and apparatus for closed-circuit ventilation therapy. In procedures involving liquid ventilation, this treatment and recirculation of the exhaled gases, vapors or liquids substantially reduces the amount of respiratory promoter needed to provide effective ventilation (col. 10, lines 13-26). Faithfull discloses that the nebulizer is used to provide fluorochemicals, heated above body temperature, to the ventilating gas in the form of a vapor. This may be accomplished by spraying or contacting a wetted surface or wick with the gas to form droplets. The fluorochemical liquid medium is particularly well dispersed in the lungs. As the fluorochemical vapor cools in the body it is deposited on the pulmonary surfaces (col. 16, lines 44-67).

Faithfull also discloses that the said method provides for the independent delivery of pharmaceutical agents or their use in conjunction with other vapors (col. 25, lines 15-30). Faithfull lacks disclosure on medicaments.

Bartus et al, discussed above, discloses a wide variety of therapeutic agents suitable for aerosol delivery.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the method and apparatus for ventilation therapy as taught by Faithfull by adding the wide variety of medicaments suitable for aerosol delivery as taught by Bartus, because of the disclosed benefits of such a method,

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including minimized trauma to the lungs and a better resolution of pulmonary and systemic disorders, and because of the need to treat a wide variety of diseases. Furthermore one of ordinary skill in the art would know that condensates have a high percentage of purity of the drug and less degradation products. Also noted that optimization of concentration ranges will not support patentability. Additionally, kits, including instructions are obvious and known to one of ordinary skill in the art.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6,716,415; 6,716,416; 6,716,417; 6,737,042; 6,737,043; 6,740,307; 6,740,308; 6,740,309; 6,743,415; 6,759,029; 6,776,978; 6,780,399; 6,780,400; 6,783,753; 6,797,259; 6,803,031; 6,805,853; 6,805,854; 6,814,955 and 6,855,310.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. Here claims 1-82 are generic to all that is recited in claims of cited U.S. Patents. That is, claims of cited U.S. Patents fall entirely within the scope of claims 1-82, or in other words, claims 1-82 are anticipated by claims of cited U.S. Patents. Specifically, the compositions for delivery and the kits comprising the compositions and devices for their delivery of the instant claims are the same as compositions and kits of the cited U.S. Patents. The instant claims recite all the therapeutic agents included in the cited Patents. Due to the excessive number of claims in the instant application and the excessive number of related Patents, the claims have to be grouped and the examination has to be general.

Claims 1-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application Nos (publication document Nos), 20030138382; 20030206869; 20040009128; 20040096402; 20040099266; 20040099269; 20040101481; 20040105818; 20040105819; 20040126326; 20040126327; 20040126328; 20040126329; 20040127481; 20040127490; 20040156788; 20040156789; 20040156790; 20040156791; 20040161385; 20040167228; 20040170569; 20040170570; 20040170571; 20040170572; 20040170573; 20040171609; 20040184996; 20040184997; 20040184998; 20040184999; 20040185000; 20040185001; 20040185002; 20040185003; 20040185004; 20040185005;

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20040185006; 20040185007; 20040185008; 20040186130; 20040191179;

20040191180; 20040191181; 20040191182; 20040191183; 20040191184;

20040191185; 20040202617 and 20040228807. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Here claims 1-82 are generic to all that is recited in claims of cited copending

Application Nos (publication document Nos). That is, claims of cited copending

Application Nos (publication document Nos) fall entirely within the scope of claims 1-82,

or in other words, claims 1-82 are anticipated by claims of cited copending Application

Nos (publication document Nos). Specifically, the compositions for delivery and the kits

comprising the compositions and devices for their delivery of the instant claims are the

same as compositions and kits of the cited copending Application Nos (publication

document Nos). The instant claims recite all the therapeutic agents included in the cited

copending Application Nos (publication document Nos). Due to the excessive number of

claims in the instant application and the excessive number of related copending

Application Nos (publication document Nos), the claims have to be grouped and the

examination has to be general.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mina Haghighatian  
March 01, 2005

*m. h. hartley*  
MICHAEL HARTLEY  
PRIMARY EXAMINER